

REMARKS

The Final Office Action mailed May 14, 2008 has been received and reviewed. In the Final Office Action the Examiner has:

- (1) maintained the rejection of claims 1,14-15, and 17 under 35 U.S.C. § 112, first paragraph, for failure to meet the enablement requirement; and
- (2) rejected claims 1, 5-6, 14, and 35 under 35 U.S.C. § 102(b) as being anticipated by any one of U.S. Patent Nos. 5,623,056, 5,601,828, or 5,242,687 to Tykocinski et al.

In connection with the present Response, claims 1, 5, and 6 have been amended. No new subject matter has been added in connection with the amendments. Upon entry of the above amendments, claims 1, 5-6, 14-15, and 17-26 remain pending in the present application.

In view of the foregoing changes and the following remarks, Applicants respectfully request reconsideration of the claims.

35 U.S.C. § 112

With respect to item (1), the Examiner has maintained the rejection of claims 1, 14-15, and 17 for failure to meet the enablement requirement under 35 U.S.C. § 112, first paragraph. In particular, the Examiner has noted that although independent claim 1 is directed to a method for inhibiting an adaptive T cell response, at no point in the claim is there a step that includes exposure of such cells to an allogenic tissue, which could mount an adaptive T cell response.

Independent claim 1 has been amended, as provided above, and is now directed to a method for producing an allograft cell designed to inhibit development of an adaptive T cell response. Since claim 1 is now directed to a method of producing an allograft cell rather than a method for inhibiting an adaptive T cell response, the step of exposing cells to an allogenic tissue, as required by the Examiner, is no longer needed. Accordingly, Applicants submit that claim 1 and its dependent claims, claims 14, 15 and 17, have now satisfied the requirement under 35 U.S.C. § 112, first paragraph, and are now in condition for allowance.

35 U.S.C. § 102

With respect to item (2), the Examiner has asserted that claims 1, 5-6, 14-15, and 17 are anticipated by any one of U.S. Patent Nos. 5,623,056, 5,601,828, or 5,242,687 to Tykocinski et al.

Independent claim 1, now directed to a method for producing an allograft cell designed to inhibit development of an adaptive T cell response, has been amended to recite, among other things, the step of providing a non-immunogenic expression vector encoding a CD8 polypeptide.

Likewise, independent claim 5, directed to a method for inhibiting the development of an adaptive T cell responses, and claim 6, directed to a method for extending the survival of an allograft in a recipient, have been amended to now recite, among other things, the step of contacting *ex vivo* a non-immunogenic expression vector encoding a CD8 polypeptide with allograft cells.

Support for the use of a non-immunogenic expression vector can be found throughout the present application, including paragraphs 134 and 148 of the published application. In particular, such an expression vector is deprived of viral genes or has had the viral coding sequences removed.

In contrast, Tykocinski et al. fail to teach, in any of their three patents, the use of a non-immunogenic expression vector in connection with the production of an allograft cell designed to inhibit development of an adaptive T cell response, in connection with the inhibition of the development of an adaptive T cell response, or in connection with the extension of the survival of an allograft in a recipient.

The Examiner has noted, in the office action, that Tykocinski et al. generally disclose the use of vectors to transform the cells, or that at least it is inherent that a vector is used when performing transformation. However, Applicants note that nowhere within any of the Tykocinski references is there any teaching or disclosure in connection with the use of a non-immunogenic expression vector in the manner set forth in independent claims 1, 5 and 6.

Accordingly, Applicants submit that claims 1, 5 and 6 cannot be anticipated by Tykocinski et al., as disclosed in any of the three references.

Claims 14, 15 and 17 are dependent from claims 1, 5 and 6. It thus follows that these claims are also not anticipated by Tykocinski et al., as disclosed in any of the three references.

Conclusion

Based on the amendments and remarks provided above, Applicants submit that the pending claims are enabling and are not anticipated by the cited references.

Accordingly, Applicants submit that the claims, as provided above, are now in condition for allowance. Withdrawal of the pending rejections, and early and favorable reconsideration are respectfully solicited. In the event that a telephone conversation would further prosecution and/or expedite allowance, the Examiner is invited to contact the undersigned at (617) 310-6000.

Applicants hereby petitions for a one (1) month extension of time for filing the present response, and authorizes the Examiner to charge \$60.00 to Deposit Account No. 50-2678 to cover the one month extension fee. Applicants do not believe that any additional extension or additional fee is required in connection with this Response. However, should any extension or fee be required for timely consideration of the present application, Applicants hereby petition for same and request that the extension fee and any other fee required for timely consideration of this application be charged to Deposit Account No. 50-2678, Reference 108674-010201.

Respectfully submitted,

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